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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,767	06/04/2001	Walter Ameling	7163-19	2333

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT PAPER NUMBER

3737

DATE MAILED: 10/21/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,767

Applicant(s)

AMELING ET AL.

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-24, 28-30, 32-34, 36-39 and 41-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-24, 28-30, 32-34, 36-39 and 41-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-3, 5-24, 28-30, 32-34, 36-39 and 41-60 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

2. The previous indicated allowability of claims 4, 8, 15, 17, 18, 25-29, 31-33, 35-37, 40-42, 48 and 49 is withdrawn. Rejections based on the newly cited reference(s) follow.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the *implantable cardiac pacemaker or defibrillator; the processing unit integrated in the respective catheters; the three reference units asymmetrically arranged or distributed in a triangle; and the pre-determined shape in the form of a circular arc* must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 11 and 14 are objected to because of the following informalities:

Regarding claim 11, it is unclear how reference units irradiating ultrasonic waves build up at least one electromagnetic field. Regarding claim 14, it is unclear how the processing unit is integrated into the catheters. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-24, 28-30, 32-34, 36-39 and 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not adequately teach how to fixedly implant the working catheter in the body. Further regarding claim

14, the specification does not adequately teach how to integrate the processing unit into the respective catheters.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-10, 12-19, 22-24, 28-30, 32-34, 36-39, 41-47 and 50-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Willis et al. of record.

Regarding claims 1-3, 6-8, 10, 12, 14-17, 19, 24, 38, 39, 42, 43, 45, 50-53, 55, 56, 58 and 60, Willis et al. disclose a plurality of working catheters (12, 14, 16) having a plurality of ultrasonic (e.g., 34, 58, 92) and electrode (e.g., 38, 56, 90) reference units located at pre-established intervals; at least one reference catheter (10), placed e.g., in the coronary sinus (col. 19 lines 43-51), having a plurality of ultrasonic (18) and electrode (30) reference units located at pre-established intervals; and a processing unit (100). See figures 1, 3-5, 9-12 and 16-19. Moreover, Willis et al. disclose wherein at least one of the work catheter(s) may comprise electrophysiology (EP) electrodes (38) for pacing and ablating (col. 9 lines 12-17, col. 13 lines 60-66) as well as for obtaining other electrical measurements (e.g., mapping signals such as impedance values, strength of wall contact, etc. col. 13 line 60 – col. 14 line 4, col. 20 lines 46-53).

Further regarding claims 9, 18, 47, 59, Willis et al. also disclose wherein the working catheters may also function as a reference catheter (col. 5 lines 20-26) and vice

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~~14~~ the specification does not adequately teach how to integrate the processing unit into the respective catheters.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-10, 12-19, 22-24, 28-30, 32-34, 36-39, 41-47 and 50-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Willis et al. of record.

Regarding claims 1-3, 6-8, 10, 12, 14-17, 19, 24, 38, 39, 42, 43, 45, 50-53, 55, 56, 58 and 60, Willis et al. disclose a plurality of working catheters (12, 14, 16) having a plurality of ultrasonic (e.g., 34, 58, 92) and electrode (e.g., 38, 56, 90) reference units located at pre-established intervals; at least one reference catheter (10), placed e.g., in the coronary sinus (col. 19 lines 43-51), having a plurality of ultrasonic (18) and electrode (30) reference units located at pre-established intervals; and a processing unit (100). See figures 1, 3-5, 9-12 and 16-19. Moreover, Willis et al. disclose wherein at least one of the work catheter(s) may comprise electrophysiology (EP) electrodes (38) for pacing and ablating (col. 9 lines 12-17, col. 13 lines 60-66) as well as for obtaining other electrical measurements (e.g., mapping signals such as impedance values, strength of wall contact, etc. col. 13 line 60 – col. 14 line 4, col. 20 lines 46-53).

Further regarding claims 9, 18, 47, 59, Willis et al. also disclose wherein the working catheters may also function as a reference catheter (col. 5 lines 20-26) and vice

versa and wherein the electrodes (i.e., mapping or linear ablation) and ultrasound units (col. 16 lines 32-34) are simultaneously actuatable.

Regarding claim 13, Willis et al. also disclose calculating a three-dimensional spline. See fig. 31 and 32.

Regarding claims 22, 23, Willis et al. disclose signal lines (e.g., 26, 62).

Regarding claims 5, 28-30, 32 and 33, Willis et al. disclose wherein reference elements (36 and 38) as well as (34) are asymmetrically arranged forming a triangle. See figures 11 and 12.

Regarding claims 34, 36, 37, Willis et al. disclose wherein the ultrasonic reference units are piezoelectric crystals (col. 6 lines 63-65, col. 10 lines 29-33) mounted in or on the catheter.

Regarding claims 44, 54, Willis et al. disclose at least twelve reference units disposed on a basket (50). See fig. 13.

Regarding claims 46 and 57, Willis et al. disclose wherein basket arms (52) form a circular arc and also wherein the catheters may have pre-shaped (curved) ends (col. 8 lines 57-59).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. of record in view of Vesely et al. '898 or Ferre et al. '756.

Regarding claims 11, 48 and 49, Willis et al. differ from the claimed invention in that electromagnetic reference units are not specifically addressed. Vesely et al. and Ferre et al. demonstrate that electromagnetic and ultrasonic reference units may equivalently be used (Vesely col. 13 lines 10-15, Ferre et al. col. 4 lines 27-31). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to replace the ultrasonic reference units of Willis et al. with electromagnetic reference units as taught by Vesely et al. or Ferre et al. as is well recognized in the medical tracking arts.

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al. of record in view of Lundquist et al.

Regarding claims 20 and 21, Willis et al. differ from the claimed invention in that control members for steering the catheter are not explicitly addressed. Lundquist et al. demonstrates that such control members (1560, 1590) are well known (see also [0034])

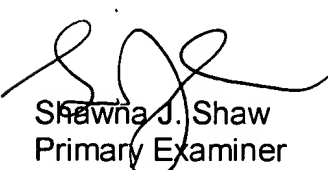
of the present specification) for improved operator control in difficult-to-navigate regions. It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to modify the catheters of Willis et al. with steering control means as taught by Lundquist et al. as is well known in the art as well as for the above described reasons.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
Art Unit: 3737
10/20/2004